

K221213 EnSite X EP SystemAug 18, 2022
113 days to decisionK221213 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k221213/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Apr 27, 2022
Decision date	Aug 18, 2022
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Abbott
Location	St. Paul, MN, US
Contact	Alexandra Agre
Website	http://www.abbott.com
510(k) history	12 submissions · 12 cleared · 2018-2026

Abbott is a global healthcare company developing life-changing medical devices and solutions. The company operates with a manufacturing facility in St. Paul, Minnesota. Abbott serves patients across multiple therapeutic areas including diabetes care, nutrition, diagnostics, and cardiovascular health. Abbott has received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's regulatory focus centers on Cardiovascular devices, which represent 91% of its FDA 510(k) portfolio. Abbott's first clearance was granted in 2018, with the mo...